Exhibit 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Joy Essman Case No. 2:12-cv-00277 Christine Wiltgen Case No. 2:12-cv-01216 Shirley Walker Case No. 2:12-cv-00873 Julie Wroble Case No. 2:12-cv-00883 Nancy Jo Williams Case No. 2:12-cv-00511	

The deposition of GREGORY BALES, M.D. taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the law offices of Drinker, Biddle & Reath, 191 North Wacker Drive, Suite 3700, Chicago, Illinois, on April 1, 2016, at 8:02 a.m.

PRESENT ON BEHALF OF THE PLAINTIFFS:

MOTLEY RICE, LLC
28 Bridgeside Boulevard
Mount Pleasant, South Carolina 29464
401.457.7700
BY: MARGARET THOMPSON, ESQ.
mmthompsonmd@motleyrice.com

TOR HOERMAN LAW, LLC
101 West Vandalia Street, Suite 350
Edwardsville, Illinois 62025
888.508.6752
By: STEVEN D. DAVIS, ESQ.
sdavis@torhoermanlaw.com
JACOB W. PLATTENBERGER, ESQ.
jplattenberger@torhoermanlaw.com

PRESENT ON BEHALF OF THE DEFENDANT:

TUCKER ELLIS, LLP
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113
216.592.5000
BY: MATTHEW P. MORIARTY, ESQ.
matthew.moriarty@tuckerellis.com

REPORTED BY:

PAULINE M. VARGO, RPR, CRR
Illinois CSR No. 84-1573

that's just a very sort of nonspecific term related to any aspect of a surgical procedure where there was some question raised.

Q. So the question would be raised as to whether the doctor was at fault with a complication of one kind or another?

A. Yes. Typically these are all, yeah, single patient/one doctor type cases and situations.

Q. Are all the opinions that you intend to offer contained in the general report that you issued?

MR. MORIARTY: Objection to form. Go ahead.

Q. Regarding general opinions.

MR. MORIARTY: Objection. Go ahead.

A. Well, I will answer all the questions to the best of my ability. If you ask me things outside the context of things I have already written, I will certainly offer those opinions, but I think most of my opinions will be consistent with what has been written down and produced.

Q. Fair enough. Are your opinions objective?

MR. MORIARTY: Objection.

A. Yes, I believe my opinions are objective. They are opinions to my best ability to give an opinion based on my own training and to my best degree of medical certainty, if you will.

Q. And are your opinions unbiased?

MR. MORIARTY: Objection. Go ahead.

A. I think my opinions are unbiased.

Q. When you prepared -- did you prepare the report yourself?

A. I did.

Q. And how did you decide what to include and what not to include in your report?

MR. MORIARTY: Objection. Go ahead.

A. Well, as you can guess, you know, there is a voluminous amount of information that can go into a report like this and there is, you know, years and years of documents, scientific papers, research articles, journal articles and abstracts, et cetera. So, you sort of pick and choose and you try to get a broad array of Level 1 evidence that reflects good science. That's what I try to include.

Q. Did you receive materials from defense

counsel as you were preparing your general report?

A. Well, there was conversations and e-mails about certain papers and abstracts and journals and such and things I looked up on my own.

Q. Did you do any kind of literature search on your own?

A. Yes. I do literature searches all the time, and I certainly, you know, do literature searches consistently in my occupation, being an academic at the University of Chicago; and certainly I did some literature search and looked back at some of these manuscripts in the preparation of my report.

Q. Did you search for particular products, for example?

A. Well, in general just we started obviously with sort of pelvic organ prolapse, and I'm familiar with a lot of literature just because I have been reviewing it and I review the Journal of Urology and Urology and Neurourology and Urodynamics. But again, and I looked at some case-specific things regarding the Prolift and, you know, the Ethicon products.

Q. Did you receive any internal Ethicon

years, so I couldn't go back and quantify the number of cases I've done. I've done, you know, well into the thousands in terms of pelvic floor procedures between prolapse and slings and sacrocolpopexies.

So, I couldn't give you the denominator and I couldn't give you the numerator unless I went back and contacted the individual every patient. So, again, you asked me for a specific number, and I wasn't able to provide that.

Q. What Ethicon prolapse products are you currently using?

A. So, I currently primarily used the TVT, which is a sling product, and the TVT obturator, which again is a sling product but the sling is placed in a slightly different fashion. It's not retropubic but it goes through the obturator foramen.

Q. So you are currently not using any Ethicon products to treat prolapse?

A. I'm not as far as I know. I think many of them are off the market. I'm not sure they are available, but no, I'm not.

Q. Do you use Gynemesh PS in your abdominal

sacrocolpopexies?

A. I used Gynemesh PS for my sacrocolpopexies for a long time. Sometimes I'm at the whim of the University of Chicago. They sometimes they get other products in, so sometimes it's not up to me.

Currently the product they have for that application is the AMS product called IntePro, but again, unfortunately, sometimes the doctors don't have any ability to -- to -- weren't involved in the decision-making.

Q. How many Prolift procedures have you performed over your career, approximately?

A. So, just to clarify, there is total Prolift, there is anterior Prolift and posterior Prolift, so there is sort of three. You want an estimate based on all those procedures put together?

Q. Why don't you give me all and then break them down as to how many of each.

A. So, I would -- roughly, again it's a rough guesstimate. This goes back again ten years or so. Probably several hundred of -- probably several hundred of all of them, and then the

breakdown would be probably 50 percent anterior Prolift, probably 45 percent total Prolift and a very smaller -- a much smaller percentage, 5 percent or less of the posterior Prolift.

Q. Have you published any peer-reviewed articles regarding using vaginal mesh for prolapse repairs?

A. Yes.

Q. What are those articles?

MR. MORIARTY: Objection.

A. Again, I mean, I think my CV -- do we have my CV here? I would have to show you. I don't remember the exact citation.

Q. Did you bring your CV?

A. I don't think I have a copy of my CV.

MR. MORIARTY: We produced it with the report and reliance list.

BY MS. THOMPSON:

Q. Okay. And do you treat mesh complications in your practice?

A. Absolutely. More complications than I care to.

Q. What are the most common mesh complications that you treat in your practice?

A. So, there is a variety. There is complications of exposures or extrusions where the mesh is sort of exposed and through the vaginal wall, and there is some pain complications that patients see which may or may not always be related to the mesh in any fashion necessarily. But patients come in with again after pelvic organ prolapse surgeries complaining of pain, and obviously the most common, I guess, is a recurrence of the prolapse, where they are coming in, they have already had a procedure and now it's failed and they need additional surgery.

Q. What type of pain complications do you treat related to mesh?

A. Well, as I said, I don't know if you can sometimes discern what's related to mesh and what isn't, but patients come in and they have pain in their pelvic floor, in their vaginal canal area, and we treat it. We treat it in combination with our physical therapists, and also we have some wonderful pain specialists. So, we treat all gamuts of pain with or without or whether or whether they have not had any kind of mesh procedure.

causing the pain on any individual patient.

Q. I want you to answer my question.

Is it your testimony considering the factors, the rate, the severity, the responsiveness to treatment, the permanence, that there is no difference between mesh repairs and native tissue repairs regarding pain?

MR. MORIARTY: Same objection. Go ahead.

A. Again, there is -- I mean, it depends on what we are talking about in terms of the pain. It's just such a broad statement. I think in general, yeah, I think it's probably the same, but I also don't think it is a good question because it's so broad.

Q. Do you hold yourself out as an expert in medical device design, Dr. Bales?

A. You know, it's funny. Whenever I've taken depositions -- you asked me earlier -- people ask are you an expert. And so, again, I'm a board-certified urologist, so the default answer is always, well, I'm an expert as a urologist, right? So, if you ask me if I'm an expert in other things and you sort of think, well, I'm not

board-certified in other areas, I'm a board-certified urologist, but I'm an expert in things that I do very commonly and things that I'm very experienced in.

So, again, medical devices, if the medical device is that I've used and very familiar with and I've held in my hand and I've placed into patients and I have done their surgeries, then yes, I guess I'm considered an expert.

Q. Have you ever designed a medical device?

A. I have not.

Q. Are you a biomaterials expert?

A. Again, sort of the same answer to the previous question. It depends on what biomaterials I guess we are talking about. But if we are talking about biomaterials that I'm familiar with, including some of the meshes and things that I've implanted in patients and held in my hand and have done hundreds of times, then I guess I'm certainly very familiar and a lot more knowledgeable than 99 percent of people.

Q. Have you ever looked at an explanted mesh device histologically?

A. So, yes, I suspect I have, and I've

certainly seen pictures of the histologic presentations, and yes, I'm sure I have been in our pathology department at least a couple times and looked at some of these things. But, you know, it will be very difficult for me to describe the histologic appearance.

Q. So you would not consider yourself an expert in pathology?

A. I'm very knowledgeable about pathology, but I'm certainly not an expert and be able to describe the specific pathologic features that a pathologist, a board-certified pathologist would be able to do.

Q. Are you an expert in regulatory affairs?

A. That's such a broad thing, what regulatory affairs are, that again I guess I can't say I'm any kind of expert in regulatory affairs. I'm not sure even what that means.

Q. How about industry standards for warnings?

MR. MORIARTY: Objection, form.

A. So, an expert in industry, you are asking me if I'm an expert in industry standards of warnings.

So, again, I'm not -- I'm not aware of what those standards may be, so I guess I'm not an expert in it.

Q. We are going to go through your report. I'm going to ask you some questions about some of your opinions contained in the report. If you want to follow along, you are welcome to.

On Page 3 --

A. Can I just -- let me make sure I'm just working off the same copy. You said you gave it that. Was that Exhibit 2? Was it Exhibit 2?

Q. Exhibit 2, correct.

A. Can I have it just to make sure? Go ahead. Thank you.

Q. At the bottom of Page 3 you start out talking about sacrocolpopexy and then you also talk about uterosacral ligament suspensions and sacrospinous ligament fixations. Do you perform either of those procedures?

A. Yes.

Q. When was the last time you performed either one and which one?

A. A long time ago, a number of years ago, five years ago.

aware of as I sit here right now.

Q. So I'm curious why you would say unfortunately these procedures have a success rate of only 60 percent at two years when Prolift is no better. Is that an objective and unbiased statement in your report?

MR. MORIARTY: Objection, form. Go ahead.

A. So, again, the statement reads that unfortunately, these two procedures had a success rate of 60 percent in two years. So, that's -- again, that's a direct citation from that paper, so I don't know how more unbiased you can be, right? I'm citing this paper and putting in the success rate. So, I'm only just rehashing what again is in the medical literature.

Q. Does that paper say "unfortunately the success rate of 60 percent"?

A. So you are concerned about the "unfortunately"?

Q. Well, I just didn't notice an opinion in your report that said "Unfortunately, Prolift only has a 60 percent success rate."

A. Prolift isn't perfect either, and again,

that's not the sentence. But I guess if I had said "The Prolift repairs have a success rate of X," I guess I could have put "unfortunately" in front of that. It's unfortunate that any surgical procedure is less than 100 percent, so I guess --

Q. But you didn't put that in your report, though, did you?

A. It looks like I didn't.

Q. In the paragraph -- and unfortunately, we don't have time to go through all the literature, but I do want to highlight some of it.

So, in your paragraph, your short paragraph about colporrhaphy --

A. Can you tell me where that is?

Q. It is on Page 4.

A. Okay.

Q. You state that high rates of recurrence of 30 percent or more have been reported with colporrhaphy, particularly in the anterior compartment. What's the recurrence in the posterior compartment in the literature?

A. I think that again, like most of these things that we are going to be discussing, there is going to be various series where the numbers are

going to vary slightly, but it's probably 20 to 30 percent, especially if you follow these patients long enough.

That's actually, unfortunately, as you know, just not to lecture, but that's actually, unfortunately, one of the problems with our medical literature, is that a lot of these series, the followup is relatively short, so there is not enough papers looking at patients over a long enough period of time where the recurrence rates obviously go up, unfortunately.

Q. So it's your testimony that the failure rate of posterior -- native tissue posterior repairs is 20 to 30 percent?

A. Yes.

Q. Are you aware of any literature where posterior Prolift improves the failure rates in a posterior repair over native tissue?

A. I think -- I think some of the literature that's out there shows it to be equivalent. Again, I don't think there is a lot of great literature on long-term outcomes with the Prolift, but I don't know if it's better, to answer your question.

Q. So I want to look at some of the -- before we look at some of the efficacy literature, let's mark this as the next exhibit.

(Bales Exhibit 7 was marked for identification.)

BY MS. THOMPSON:

Q. You are certainly aware that some doctors feel that mesh complications are more serious than native tissue repair complications, correct?

MR. MORIARTY: Objection, form.

A. I suspect there is some doctors who feel that way, sure, definitely.

Q. Do you know Linda Cardozo?

A. No.

Q. Do you know her name?

A. I know the name.

Q. I'm going to show you an e-mail from 2005. When was the Prolift marketed, introduced into the market?

A. I think the end of 2005. I don't remember exactly. You might know better than me. I want to say it was sometime in 2005, towards the end of 2005.

then say but I want to get started using it. So that's why, again, it is hard for me to interpret this.

Q. Was there any efficacy data when you began using that Prolift device in 2006?

A. There is never -- any new procedure we do, there is never any real good efficacy data on any new procedure.

Q. I want to go over some of the literature on the colporrhaphy and the efficacy, and I'm using -- I'm going to start with the Weber article that you cited in your report; and you are aware, Dr. Bales, that the Weber article from 2001 was re-analyzed with modern definitions of prolapse and success by Chmielewski, correct?

A. Yes.

Q. I'm curious why you cited the 2001 Weber article rather than the 2011.

A. So, I guess if that's a question, again, it's impossible to cite every article that's out there, so I picked certain ones.

MS. THOMPSON: And if you could mark this as Exhibit No. 8. I just have two copies of this, sorry.

(Bales Exhibit 8 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And let's just go to the conclusions, and could you read the last paragraph for us.

A. Would you like me to read the entire last paragraph?

Q. Um-hmm?

A. Starting "In conclusion"?

Q. Um-hmm.

A. "In conclusion, this study provides further evidence that success after prolapse surgery depends heavily on the criteria that are used to define treatment success. In the frequently cited study by Weber, et al., when strict anatomic criteria were used, success was low. However, when contemporary, clinically relevant criteria for success were used, treatment success was considerably better, with only 11 percent of subjects experiencing anatomic recurrence beyond the hymen, 5 percent of subjects

experiencing symptomatic recurrence, and no subjects requiring surgery for recurrence or complications at one year.

"Given this and the excellent safety profile of traditional vaginal prolapse surgery, we conclude that anterior colporrhaphy that is performed in conjunction with other native tissue repairs is appropriate as a primary treatment of symptomatic anterior vaginal prolapse."

Q. And my question is, why did you cite the Weber paper in 2001 when this paper is more recent and more authoritative?

MR. MORIARTY: Objection, form and asked and answered. Go ahead.

Q. Well, let me just say, is your -- is your -- the reason that you didn't use this paper is you just can't cite everything? I think that was your answer before. Is that it --

A. Yeah --

Q. -- why you chose the old paper?

A. Yeah, I apologize. I chose -- I tried to choose a appropriate synopsis of a variety of different things. I'm sure there are other papers that I missed that might be more current or what

have you. But again, there is a lot of literature that's out there. I had to cite certain things.

Q. And you will certainly agree with me that a 5 percent symptomatic recurrence and no subjects requiring additional surgery is very different from the recurrence of 30 percent or more that you cite in your paper, right?

A. So you are asking if 30 is different than 5, and the answer is yes, 30 is different than 5.

Q. And you believe that you reported objectively on the success rates with colporrhaphy?

A. Yes. I think this paper, actually, this later information actually is somewhat of an anomaly; and I think most -- most papers and again, there is, you know, lots of data and lots of studies that aren't cited here, would suggest that the number is higher than 5 percent. And again, there is going to be a variety based on the paper.

Q. Okay. Well, let's go to one of the other papers that you cited and Fed Ex'd. I thought this one was apparently really important, and I just have two copies of this one, I'm sorry to say.

We will mark that as the next exhibit, 9, and you are familiar with this paper because you cite it in your paper, in your report, right?

A. Yeah. Peter --

MR. MORIARTY: It's so big you can hardly miss it.

MS. THOMPSON: The first paper was that -- I have two of these that are large size. The first one was from Duke. I thought they just thought it was from Duke that it was important.

THE WITNESS: These guys work with us. They are part of the University of Chicago now, Peter Sand and Roger Goldberg and Janet Tomezsko.

(Bales Exhibit 9 was marked for identification.)

BY MS. THOMPSON:

Q. I actually want to turn your attention to that discussion of this paper --

A. Okay.

Q. -- by Dr. Shull. Do you know Dr. Shull?

A. I don't.

Q. Have you seen Dr. Shull cited in Ethicon

series of over 300 women" --

MR. MORIARTY: I'm sorry. Can you please tell us what you are reading from?

MS. THOMPSON: Several factors are related to long-term outcome.

MR. MORIARTY: We need to know where you are reading from.

MS. THOMPSON: I'm telling you. In the comments section it says several factors are related to long-term outcome, and I'm reading from number one.

BY MS. THOMPSON:

Q. "In our most recent series of greater than 300 women in whom we specifically repaired the transverse portion of the pubocervical fascia, along with other defects, the rate of anterior compartment persistence or recurrence was 7 percent for prolapse halfway to the hymen and 2 percent for prolapse to the hymen. We used no mesh."

You will agree with me that a success rate of 7 percent halfway to the hymen and 2 percent for prolapse to the hymen with a native tissue repair is significantly less than the 30 percent that you cited in your expert report,

correct?

MR. MORIARTY: Objection, form.

A. I think 30 percent is a more accurate representation of what the experience is nationwide for sure, as you just read.

Dr. Shull is a very accomplished urogynecologist who I don't know personally, but he is citing his own work, and he obviously gets excellent results with his native tissue repair.

I'm not sure how long these patients were followed, but he cites 7 percent in his experience, and 7 percent is a lower number than 30 percent.

MS. THOMPSON: I've just handed another paper. Would you mark this as Exhibit No. 9.

MR. MORIARTY: 10.

(Bales Exhibit 10 was marked for identification.)

BY MS. THOMPSON:

Q. Dr. Bales, are you familiar with Exhibit 10, a paper by Funk and Visco?

A. Yes.

Q. And this paper looked at 27,809 anterior

prolapse surgeries. The 5-year risk of surgery for recurrent prolapse was similar between vaginal mesh and native tissue groups with 10.4 percent recurrent with mesh and 9.3 recurrent with native tissue. You will agree that those numbers are significantly less than the 30 percent that you cited in your expert report, correct?

A. Yes.

Q. And that there was -- in this paper of 27,000-plus patients, there was no difference between mesh and native tissue repairs, correct?

A. Yes, it looks like they are, right, essentially similar.

MS. THOMPSON: And Exhibit No. 11.

(Bales Exhibit 11 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper by Dr. Oversand?

A. Yes.

Q. And Dr. Oversand had a satisfaction rate of 94 percent of patients with native tissue anterior repairs and a 5-year reoperation rate of 2.6 percent in one group and 8.9 percent in the

other group and concluded that POP surgery using native tissue repair entails low reoperation rates with excellent subjective and objective results and should be the primary -- should be the first choice in treating primary POP providing use of adequate surgical technique as was published in 2013.

That's certainly different from what you cited in your expert report, correct?

MR. MORIARTY: Objection, form.

A. Again, the numbers are lower in this paper in terms of the recurrence rates, yes.

MS. THOMPSON: And Exhibit No. 12.

(Bales Exhibit 12 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And this is the three-year followup on Dr. Iglesia's original Prolift study, correct?

A. Yes. I'm just trying to see if they are all Prolift people, to make sure on the methods.

Yes, okay.

Q. And you are aware that this study was

halted prematurely because of 15.6 percent mesh erosion rate which exceeded their predetermined limit, correct?

A. Yes, it is prematurely halted.

Q. And -- but they continued to follow the patients for efficacy, correct?

And these authors concluded that there was no difference in three-year cure rates when comparing patients undergoing traditional vaginal prolapse surgery without mesh with those undergoing vaginal colpopexy repair with mesh, correct?

A. Right. You can read their conclusion. They saw no difference.

Q. And this paper wasn't included in your expert report, was it?

A. I don't think so.

Q. And it is still your opinion that colporrhaphy has a recurrence of over 30 percent and that mesh repairs are preferable?

MR. MORIARTY: Objection, form.

A. It's my opinion that, yeah, anterior recurrence rates are as high as 30 percent.

Q. Or you said 30 percent or more, not as high as 30 percent.

Q. And that would be consistent also with the paper we just looked at previously, at the Abed paper, correct?

MR. MORIARTY: Objection. Are you just talking about the dyspareunia rate?

MS. THOMPSON: Just the dyspareunia. Sorry.

A. Yes.

Q. If we go to the Jacquetin 2013 paper -- we will mark this one too, 17. I think you are familiar with this one because it is cited in your expert report, correct?

A. Correct.

(Bales Exhibit 17 was marked for identification.)

BY MS. THOMPSON:

Q. And this Jacquetin paper with the followup of the TVM, total transvaginal mesh series, this is the one that your chart was derived from, correct?

A. Yes.

Q. And in this paper, in the results section of the abstract, Dr. Jacquetin reports 16 percent with mesh exposure for which 8 resections

needed to be performed, 7 exposures still ongoing at the 5-year endpoint, all asymptomatic, correct? I'm reading that correctly?

A. You are reading that correctly, yes.

Q. And only 33 out of 61, 54 percent, sexually active patients at baseline remained so at 5 years in his study, correct?

A. That's correct.

Q. And de novo dyspareunia was reported by 10 percent, correct?

A. That's correct.

Q. And you are aware that Jacquetin also published a paper based on the experience titled "Complications of Vaginal Mesh"?

A. Do you have it? Did you want to go over it?

Q. I need a helper.

A. Maybe this young fella.

MS. THOMPSON: It is just a short paper. I do have one additional copy, and we will mark that as Exhibit 18.

(Bales Exhibit 18 was marked for identification.)

BY MS. THOMPSON:

Q. Do you need a moment to look at that, or are you familiar with this paper?

A. Yeah, I'm familiar. I'm skimming it over, but if I need more time I won't answer your question and I will ask for a few more minutes, but you can ask your question.

Q. This paper is based on Jacquetin's experience with removal of 160 explant -- implants, correct?

A. I will need just a second to confirm that number.

Yeah, I mean, it seems that he is just discussing more broadly everything about some of his experiences and citing some other work, but then on Page 895 he discusses that the French experience is 160 implants that were removed by his group, yep.

Q. And under the complications he lists infections, correct, on Page 894?

A. Correct.

Q. And he lists exposures and erosions, correct?

A. Yep.

Q. And he lists retractions, correct?

A. That's correct. We are reading, yes, those are the three things.

Q. And he describes the average shrinking of 25 to 30 percent in experimental surgery, and it may reach 40 percent of the initial surface of the implant in patients after surgery.

MR. MORIARTY: Is that a question?

Q. And therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering. Is that what Dr. Jacquetin describes in this paper?

MR. MORIARTY: Objection, form.

Q. Did I read it correctly?

A. I think that bullet point you read exactly, so that's what he has written here, yeah.

Q. And we will talk about your opinions on shrinkage in a minute, but at least Dr. Jacquetin listed that retraction as a complication of the mesh devices he studied, correct?

A. Sure, and you left out -- right, and he describes on a rat's abdominal wall and then he is guesstimating based -- he says it may reach 40 percent on patients. So, it sounds like at

least on the experimental side it's on the rat's abdominal wall, but you read the rest of the sentence accurately.

Q. So, you think when he says -- sorry. So, you think when he says, therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering he is talking about rat surgeons?

MR. MORIARTY: Objection, form.

MS. THOMPSON: Well, I'm just asking if that's what he meant, what he said.

MR. MORIARTY: You asked him if you read that exactly, and you didn't. You skipped the part about the rats, so he was just pointing out what you skipped.

MS. THOMPSON: I don't think I did.

MR. MORIARTY: That's why I objected to form. You skipped the part about the rats.

MS. THOMPSON: Well, I didn't intend to skip.

BY MS. THOMPSON:

Q. You don't think the second sentence is applying to rats, do you, Dr. Bales?

A. Well, the second sentence specifically

says patients; the first sentence definitely says rats. So, I guess that was the only clarification.

Q. So you think the 40 percent would refer to patients, human patients, right?

A. Well, again, I mean, he is not citing any specific study here. It sounds like he is surmising it may reach. I don't --

Q. But he is talking about humans, right?

A. He says in patients, so I would assume that means patients.

Q. And when he says many surgeons will use large implants to cover defect and anticipate scarring, shrinking and puckering, he is talking about human patients also; agree?

A. I suspect, although again, it's a very general statement, and I'm not sure which surgeons he is referring to or anything, how large. I mean, it's just kind of a very general statement. I imagine he is referring to surgeons operating on humans. I don't want to over-infer.

Q. Okay. I want appreciate that.

(Mr. Jake Plattenberger entered the deposition proceedings.)

MR. MORIARTY: Can we help you?

MR. DAVIS: He is with me.

BY MS. THOMPSON:

Q. Going back to your report, Dr. Bales, on page -- the bottom of Page 7, let's go to Page 7, in the first paragraph, dyspareunia rates were very acceptable. What is an acceptable dyspareunia rate for you following any type of surgery?

A. Well, obviously, it would be better certainly for patients not to have dyspareunia, but any -- I guess we all have a different opinion.

I'd tell you my opinion would be any type of vaginal surgery we are doing, if we are getting dyspareunia rates under 10 percent, it's probably very acceptable. But again, that's very sort of general, and again, a lot of patients, as we just cited on some of the previous studies, don't remain sexual active. A fair majority of the patients aren't sexual active.

But to answer your question, I guess anywhere in the low teens to less than 10 percent would be acceptable for a vaginal surgical procedure like this.

Q. And you would agree that there is a likelihood that at least some of those patients who

So, there is a scale, of course, but my point was when you are trying to compare and discern whether it's from associated with a hysterectomy or a native tissue repair or a mesh, I think on balance those can be the same. And that was the question you asked me. You didn't ask me is dyspareunia from patient to patient exactly the same.

Q. But you answered dyspareunia is dyspareunia.

A. Meaning, again, that -- let me clarify that. Dyspareunia needs to be taken seriously, and that's my only point, that when dyspareunia occurs, it's something that if a person has pain with intercourse, we need to take that seriously.

So, I don't -- I don't say, oh, it's mild or major. Dyspareunia is a serious problem for a woman, and that's why if you have dyspareunia, it's bad and it's something we will try to correct. That's the point I was trying to make, and I probably didn't answer it very articulately.

Q. Dyspareunia may not always be bad; some dyspareunia is very easy to treat, correct?

A. Yes, but it's still bad. It may be easy to treat, but it doesn't mean it's not bad.

Q. Do women with vaginal atrophy ever have severe, horrific vaginal pain with intercourse?

MR. MORIARTY: Object.

A. Yes.

Q. That cannot be treated easily with local estrogen therapy?

A. That's the first thing we do with those patients with atrophic changes, and very often that can solve the problem, but not always.

Q. Do you treat women with dyspareunia that don't have a urologic source?

A. Yes.

Q. You treat women with atrophic vaginitis when that's the only condition they are presenting with?

A. Yeah. So, they typically would come see me because maybe they had a kidney stone or they have had a urinary tract infection, and then in taking their history we find out they also have dyspareunia. We do a vaginal exam, and if they have atrophic vaginitis, of course we treat it.

That's part of our history-taking and

thorough physical exam. There is no urologic cause for dyspareunia. I mean, bladder pain and dyspareunia are slightly distinct, right, so dyspareunia --

Q. Or postoperative urologic surgery?

A. Correct.

Q. So, your opinion that the quality of dyspareunia and vaginal pain that occurs after mesh surgery is no different from that that can occur with other prolapse surgery?

A. Yes. It may not be any different at all.

Q. And you are ignoring the dozens of articles that would say something differently, correct?

MR. MORIARTY: Objection, form. Go ahead. It's argumentative.

A. I'm not sure they say anything a whole lot differently. There is papers that cite pain and dyspareunia after any type of vaginal surgeries and stuff; and certainly among those, as you stated earlier, are papers now looking at experiences with vaginal mesh procedures.

Q. Can you cite any paper that would

support your opinion that the pain associated with vaginal mesh is no different -- and we are considering all the factors, not that just that it occurs. Can you cite any paper that says that pain that occurs after mesh procedure is no different from that occurring with any other native tissue repairs?

A. I'm not sure there has been a comparative study, so I can't say that.

Q. It doesn't even have to be a comparative study. Has anybody offered an opinion that the mesh pain after mesh surgery is no different when you consider all the factors that we have talked about, the native tissue repairs?

MR. MORIARTY: Objection. Go ahead.

A. So, if I see a patient who has vaginal pain and fibromyalgias and says she can't get near her husband and she is on the verge of divorce and she is coming to see me because she was told I'm a pelvic floor reconstructive guy and what can I offer her and that woman has never had vaginal mesh surgery, any surgery, and she has horrific dyspareunia that's affecting her marriage, that woman's dyspareunia is no different than a patient

who has had mesh and comes in and complains of the exact same pain.

Q. How many postmenopausal women do you see with new onset of dyspareunia due to pelvic floor myalgia?

A. That would be hard for me to quantitate the number. A fair number.

Q. When was the last time you saw someone, new onset, menopausal, pelvic floor myalgia, horrific dyspareunia, in your practice?

A. Probably Monday.

Q. I would like to see her records.

MR. MORIARTY: Motion to strike.

Q. You cited the Maher Cochrane reviews on pelvic organ prolapse repairs in your paper?

MR. MORIARTY: Are you talking about in his report?

MS. THOMPSON: In his report, sorry, in your report, and the Cochrane 2016 review of pelvic organ prolapse, and we can go ahead and mark this.

(Bales Exhibit 21 was marked for identification.)

BY MS. THOMPSON:

Q. And I'm just giving you the summary of the review, and let's look at the key results. The Cochrane review 2016 states that overall the quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision, correct?

MR. MORIARTY: I'm sorry. I hate to stop you. Could you tell me exactly where you are reading? Obviously you are on the last page.

MS. THOMPSON: The very last sentence of the last page.

MR. MORIARTY: Oh, you are under main results. I thought you said under key results.

MS. THOMPSON: That what I was reading was just quality of the evidence on the last page.

BY MS. THOMPSON:

Q. Did I read that correctly, Dr. Bales?

A. Yeah, I'm sorry. I was on Page 2. I was reading under main results.

Q. Under quality of the evidence on Page 3, "Overall the quality of evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision." Did I read that correctly?

MR. MORIARTY: I object. I don't know where you are, what you are reading. I don't see a section called quality --

MS. THOMPSON: Plain language summary on the very last page.

MR. MORIARTY: Okay. So you are on the fourth page of this document under now "Quality of Evidence" at the very end?

MS. THOMPSON: That's where I have been the whole time.

BY MS. THOMPSON:

Q. "Overall, the quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision."

Did I read that correctly?

A. Yes.

Q. And did the authors conclude -- I'm back on the previous page on author's conclusions.

"The authors conclude that the risk/benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risk, there is currently no evidence to support this position."

Did I read that correctly?

A. You read it perfectly.

Q. And in the last paragraph, "In 2011, many transvaginal permanent meshes were voluntarily withdrawn from the market and the newer lightweight transvaginal permanent meshes still available had not been evaluated within an RCT. In the meantime, these newer transvaginal meshes should be utilized under the discretion of the ethics committee."

Did I read that correctly?

A. Yes. You read it fine.

Q. In 2016 the authors of the Cochrane study, with Prolift having been on the market for 11 years and Gynemesh on the market for 16 years, are stating that these meshes should only be utilized under the discretion of an ethics committee, correct?

MR. MORIARTY: Objection.

Q. Is that not what the authors concluded?

A. The authors' conclusion says as you read them. They state new or transvaginal meshes should be utilized under the discretion of the ethics committee. That's what's written here. And it's 14 years with the Gynemesh, 2002 to 2016, 14 years.

Q. What did I say?

A. 16.

Q. I stand corrected.

MR. MORIARTY: And you said like 11 to 12 for Prolift.

MS. THOMPSON: Well, it was introduced in 2005, so that would be 11.

MR. MORIARTY: And taken off the market in 2012.

MS. THOMPSON: I intended to say 11 years after it was introduced to the market. If I said 11 years of use, I am mistaken. There are certainly women who have had it for 11 years.

We will mark this next as 22.

(Bales Exhibit 22 was marked for identification.)

outcomes" --

A. Yes.

Q. -- "from these systematic reviews are not as reassuring for the safety and efficacy of transvaginal mesh as data presented from initial case reports published by authors with a financial COI..."

That means conflict of interest, right?

MR. MORIARTY: Objection, form.

A. That's what conflict of interest --

Q. Does "COI" mean conflict of interest in this context?

A. Yes.

Q. "...with the product being evaluated."

Did I read that correctly?

A. Yes.

Q. And then it discusses the FDA 2011 transvaginal mesh alert. You are familiar with that document, correct?

A. Correct.

Q. And it says, "Unfortunately," reading that paragraph that starts, "Unfortunately, much of the current data on POP surgery presented in our systematic reviews fails to allay concerns outlined

in the September 2011 FDA transvaginal polypropylene mesh report that found the safety of transvaginal meshes has not been established; depending on the compartment, the efficacy of transvaginal meshes has not been established to be more effective than traditional repairs; vaginal mesh from POP repair should be reclassified from class II to class III to ensure premarket analysis includes a non-mesh control arm; currently marketed vaginal mesh products should undergo premarket evaluation to better explain" --

A. Postmarket.

Q. Sorry. Thank you.

-- "postmarket evaluation to better explain the risk/benefit of mesh versus POP repair without mesh; and safety and efficacy of mesh at sacral colpopexy had been established."

Do you disagree with these conclusions made by Maher, the author of the Cochrane reviews on prolapse mesh use?

A. Which specific ones? The entire --

Q. The ones I just read from this paper.

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah, I have some disagreements on some of them. I mean, basically, if you want, we can go over them one by one. There is five bullet points.

The safety of transvaginal meshes has not been established. Well, there has been a wealth of studies on transvaginal meshes. We have been talking about them in a number of the studies. So, I think the safety has been established, and we could argue about, you know, each of the papers, but there is a lot of data out there, so --

Q. So, you disagree, that the safety has been established. You disagree with the authors of this paper and the Cochrane reviews, correct?

A. That's a different question. I thought we were talking about this right now.

Q. Well, I'm just saying since that's their opinion in this paper, you would disagree with the authors on that point, correct?

MR. MORIARTY: Objection, asked and answered.

A. Yes. I thought we would go point by point.

Q. And so you would disagree with the FDA as well on that point, correct?

A. No. I think -- well, the FDA report was from 2011, and I think the FDA report in 2011 just acknowledged that it was still early; and as you know, with that FDA report, it's cited that there is a variety of different complications that we need to be aware of. And to specifically this says the safety has not been established, I mean, yes, I would disagree. If you have a lot of patients and a lot of experience on safety, then to some degree I would disagree; I think it has been established. I think you have studies out there.

Q. And do you disagree that depending -- the second bullet.

A. Well, let's go through it. "Depending on the compartment the efficacy of transvaginal meshes has not been established to be more effective than traditional repairs." I think there is still, you know, better studies that need to occur, but for sure there is conflicting results on the effectiveness and whether transvaginal meshes are better. I would be fine with that, so, and as it says, depending on the compartment there is a lot of factors that, you know, like what specific, whether you are doing rectocele, cystoceles, what

have you.

Vaginal mesh repairs --

Q. Another point. But you will agree with me, there is no studies that establish superiority of vaginal mesh for effectiveness in the posterior or apical compartments?

MR. MORIARTY: Objection. Go ahead.

A. Yeah, there is not a lot of good head-to head studies that suggest it's superior.

Q. Are there any?

A. There are studies that suggest it's equivalent.

Q. Not superior?

A. Not superior. "Vaginal mesh for pelvic organ prolapse repair should be reclassified." Again, I don't -- you know, that's sort of not my area of knowledge base in terms of what goes into the classification scheme, if you will, so I don't have a good opinion on that.

"Currently marketed vaginal mesh products should undergo a postmarket evaluation," that's okay, I mean, but I don't have a strong opinion of that one way or the other.

And the last bullet point, "Safety and

efficacy of mesh at sacral colpopexy had been established." As we stated, I mean, again, there is a lot of data on sacral colpopexy, so I would agree that has been established, but as I said, I also would agree that the first point, there is at least data now that has established to some degree the safety and efficacy.

So, I hope that was clear. I just wanted to make sure you understood sort of --

Q. Were there any studies when Prolift was introduced in 2005 establishing safety and efficacy of the device?

A. Well, it was a new device, so I'm not aware that again it was being trialed and such, so...

Q. So the answer would be no?

A. So, no.

Q. And finally, are you familiar with this paper?

MS. THOMPSON: And we will mark that as Exhibit 23.

(Exhibit 23 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper titled "Vaginal Mesh Contraction, Definition, Clinical Presentation and Management"?

A. Yes.

Q. And one of the two authors of this paper is also the author of the Cochrane reviews that you cited in your paper as well?

A. Maher.

Q. Maher. Is it your opinion that vaginal mesh contraction is not unique to vaginal mesh devices?

A. It is not -- say that again.

Q. You've given the opinion that the only complication unique to vaginal mesh devices is exposure and erosion, and I'm asking you is vaginal mesh contraction not unique to vaginal mesh devices?

A. I guess anything having to do with the mesh itself is unique to the mesh. We could argue about the extent of contracture, if you will. But if the mesh changes at all, it's only going to change if the mesh is present. So, again, I'm not sure that's a complication, but it's a behavior of

the mesh. Maybe that's more accurate.

Q. Vaginal mesh contraction characterized by severe vaginal pain, aggravated by movement, dyspareunia in all sexually active women and focal tenderness over contracted portions of the mesh on vaginal examination, commonly involving the lateral fixation arms, you have a question about whether that's a complication or not?

A. I don't have a question. If the pain exists, I have a question how much is specifically due to contracture, which is what you were just talking about.

Q. Well, these authors are reporting vaginal mesh contraction. Do you question their report?

A. I mean, their report is their report.

Q. And it certainly wasn't included in your expert report, was it?

A. It was not.

Q. Vaginal mesh contraction characterized by severe vaginal pain, dyspareunia in all women and focal tenderness over contraction. In fact, you say it's not even established that mesh contracts to any clinical significant degree;

correct?

A. That's what I said.

Q. You certainly consider vaginal mesh contraction a significant clinical condition, correct?

MR. MORIARTY: Objection. Go ahead.

A. I guess that we can argue about how much and how relevant contracture, how much it occurs, how well it's measured, and if that truly is clinically significant. Certainly these authors feel that they felt some of the pain that they are seeing is related to contracture.

Q. And you are aware that there are dozens, literally, of articles describing mesh contracture and the clinical symptoms, primarily pain, associated with it, correct?

A. I'm aware that both those things exist, and I'm certainly aware that mesh contractures occur, just like mesh contractures occur in inguinal hernias and ventral hernia and whatever, yes.

Q. Okay. We are talking about vaginal mesh contractions, right?

A. Yes, and I'm aware that they contract a

little bit.

Q. A little bit?

A. Well, I don't think it's certain. It's very unclear how much they contract. It hasn't been -- it's not well-studied, in percentages and things like that. But yes, that we can say it's safe to say vaginal meshes can contract. I will certainly agree to that.

Q. Okay. Well, you state in your report, and I'm just questioning whether this is objective and unbiased, that there is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees.

So, Maher's paper is not conclusive to you that it occurs?

MR. MORIARTY: Objection, form. Go ahead.

A. Again, there is two different points you are saying there. We are saying that --

Q. I first read your statement and then I want to --

MR. MORIARTY: Don't cut him off. He needs to answer your question.

MS. THOMPSON: I apologize.

MR. MORIARTY: If you don't like the answer, you can follow up.

MS. THOMPSON: I'm just trying to get through because I have three hours to cover about 12 products.

THE WITNESS: It contracts.

MR. MORIARTY: Three, I believe.

MS. THOMPSON: Anterior, posterior, total, six, seven, eight.

MR. MORIARTY: Prolift, Gynemesh PS.

MS. THOMPSON: Prolift, anterior, posterior, total, which he said was three different products, Plus M. Well, okay. That's three products that would give me seven hours. Okay. Go ahead.

A. That meshes, and we are talking about vaginal meshes, contract, to the extent of their clinical relevance, I guess I'm not -- I'm not -- I'm not convinced that we have a good understanding of the clinical relevance.

Q. So in the literally dozens of papers that talk about contraction, retraction, shrinkage, you are not convinced that that's a clinically significant condition?

A. I'm not convinced that in all those patients it's simply -- it's as simple as saying a little contraction occurred, and that's what's causing all the pain. I think that it's not very well defined. That's my opinion.

Q. Okay. The one paper you did out of the literally dozens of papers that discussed this, including the FDA, as a clinically significant condition that is unique to mesh, the one paper you selected to include in your expert report is Dietz. My question is --

A. So you are happy with this one, that I included this one?

Q. Oh, let's talk about this one.

A. Okay. Please.

Q. Did you find this paper on your own or were --

MR. MORIARTY: Is this marked?

MS. THOMPSON: Let's mark that as the exhibit next.

(Bales Exhibit 24 was marked for identification.)

BY MS. THOMPSON:

Q. My question, first of all, is this a

paper you found on your own literature search, or was this something that was furnished to you by defense counsel?

A. I don't recall. I think I found it on my own.

Q. And this is the one you chose out of dozens, if not hundreds, of articles that discuss mesh shrinkage, contraction, retraction and the clinical significance, correct?

MR. MORIARTY: Objection, form.

A. This is one that's cited in my Herrera report.

Q. Let's look at this report from 2011. You are aware that Dr. Dietz is a consultant for mesh manufacturers, correct?

A. Yes. Well, I'm just reading it. Actually, I didn't remember that, but I'm reading underneath on the first page here. It says he has acted as a consultant for various vendors, so yes, I guess he is.

Q. And Dr. Dietz used translabial ultrasound in this study, correct?

A. Correct.

Q. Wouldn't that transvaginal ultrasound be

A. Oh, I think we are learning more and more. I don't know exactly what the timeframe was on this, but for sure it's newer, right, that we are putting these materials into the vagina, so I think we have an evolving knowledge. I guess that would be more correct to say.

Q. When the Prolift was on the market, Gynemesh and Prolift for transvaginal use, was there poor knowledge of the vaginal in vivo response to the materials?

A. I think there was limited knowledge.

Q. So you take exception with the word "poor" but agree that it was limited?

A. I would use the term, yeah, "limited." I wouldn't be comfortable saying "poor." It is limited.

Q. Do you agree that the vagina has an important vascularity and endogenous microflora that may have an impact on host tissue response and biomechanical properties of grafts used in pelvic reconstructive?

A. Yeah, I agree with that 100 percent.

Q. Going to the next page, "What do we observe with mesh repair in our field?" And the

statement is "Mesh shrinkage may be associated with," bullet points, "stiffness/tenderness at vaginal examination." Would you agree with that?

MR. MORIARTY: Objection, form. Go ahead.

Q. Would you agree with mesh shrinkage may be associated with stiffness and tenderness at vaginal examination?

MR. MORIARTY: Same objection.

A. I guess I would agree. May be associated, I guess I could agree with that statement.

Q. Would you agree that mesh shrinkage may be associated with discomfort, pain during intercourse?

MR. MORIARTY: Same objection.

A. I guess I would just underscore again that I don't know how easy it is to determine whether mesh shrinkage is what's causing discomfort and pain after intercourse, so that's why. So, I guess may, may be associated, sure. I guess I could on balance say that's okay.

Q. And you certainly agree that there are many papers where the authors are able to make the

connection between the shrinkage, retraction, contraction and pain; you just are not able to, correct?

MR. MORIARTY: Objection, form. Go ahead.

A. Yes, I'm not able to.

Q. Do you agree with the statement mesh shrinkage may be associated with pelvic pain?

MR. MORIARTY: Same objection.

A. I think it was the same thing we said before. There is -- when patients have pain, specifically the mesh being possibly shrinking or is shrinking, is that the cause of the pain, I guess it can be hard to say. So, that's my only concerning about making that blanket statement.

Q. Do you agree or disagree with the statement mesh shrinkage may be associated with urinary or defecatory dysfunctions?

MR. MORIARTY: Same objection.

A. I -- yeah, I guess I'm not sure if the mesh -- yeah, I guess I'm not prepared to say mesh shrinkage causes urinary or defecatory dysfunction, so no.

Q. Do you disagree or agree with the

statement mesh shrinkage may be associated with prolapse recurrence?

MR. MORIARTY: Form objection. Go ahead.

A. I would say that mesh shrinkage or mesh loosening, so yes, I would agree with that, could be associated with prolapse recurrence. I would say yes to that statement.

Q. And these authors cite three papers to support the statements that they make on this page of this presentation, correct?

A. I guess. I mean, it looks like these are slides, right? I mean, again, it seems to me that maybe this was IUGA, right. It was at a meeting and these are just copies of slides, I think, so these obviously are the papers they cite. I would have to go back through those papers are, but sure, it looks like they are giving those citations.

Q. Yeah, and my question was just the authors cite three papers.

A. Citations are definitely there.

Q. And I'm using the word "presentation" on when we are talking about this document, if that's

MS. THOMPSON: No, we don't.

(At 12:36 p.m. the deposition was concluded.)

CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

I, PAULINE M. VARGO, a Certified Shorthand Reporter of the State of Illinois, C.S.R. No. 84-1573, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

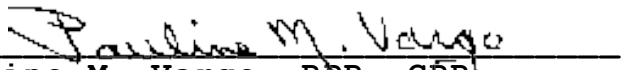
That the foregoing deposition transcript was reported stenographically by me and thereafter reduced to typewriting under my personal direction;

That the reading and signing of said deposition was reserved by counsel for the respective parties and the witness;

That the foregoing constitutes a true record of the testimony given by said witness before this reporter;

That I am not a relative, employee, attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

CERTIFIED TO THIS 6th DAY OF APRIL, A.D., 2016.



Pauline M. Vargo, RPR, CRR
Illinois Certified Shorthand
Reporter No. 84-1573